# THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS CENTRAL DIVISION

DARLENE BERNARD

Plaintiff,

VS.

Civil Action No. 07-40254

MERCK & COMPANY, INC., and PFIZER, INC.,

Defendants.

# DEFENDANT PFIZER INC.'S ANSWER TO PLAINTIFF'S COMPLAINT AND JURY DEMAND

Pursuant to Fed. R. Civ. P. Rules 7(a) and 8(b), defendant Pfizer Inc. ("Pfizer" or "Defendant") hereby responds to plaintiff Darlene Bernard's ("Plaintiff") *Complaint and Jury Demand* as follows:

# PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Defendant reserves the right to seek leave to amend its Answer and its additional defenses when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

#### **PARTIES**

- 1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship, Plaintiff's medical condition, and whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant denies that Celebrex® caused Plaintiff injury or damage and denies the remaining allegations in this paragraph of the Complaint.
- 2. Defendant states that allegations in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no response is required. To the extent a response is

necessary, Pfizer states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies the same.

Defendant admits that Pfizer is a Delaware corporation with its principal place of business in New York. Defendant admits that Pfizer is registered to do and does business in the Commonwealth of Massachusetts. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendant denies the remaining allegations in this paragraph of the Complaint.

#### **JURISDICTION AND VENUE**

4. Defendant is without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs. Defendant admits that Pfizer does business in the Commonwealth of Massachusetts. Defendant denies any wrongful conduct, denies committing a tort in the Commonwealth of Massachusetts, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

5. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies the allegations in this paragraph of the Complaint.

# **INTRODUCTION**

- 6. Defendant states that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 7. Defendant states that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 8. Defendant states that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the

FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

- 9. Defendant states that allegations in this paragraph of the Complaint regarding Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant admits that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendant states that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendant denies the remaining allegations in this paragraph of the Complaint.
- 10. Defendant states that allegations in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no response is required. To the extent a response is necessary, Pfizer states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies the same.
- 11. Defendant states that allegations in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no response is required. To the extent a response is necessary, Pfizer states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies the same.
- 12. Defendant states that allegations in this paragraph of the Complaint regarding Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant denies that Celebrex® caused

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Plaintiff injury or damage and denies the remaining allegations in this paragraph of the Complaint.

- Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 14. Defendant states that allegations in this paragraph of the Complaint regarding Merck are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

# <u>ALLEGATIONS REGARDING VIOXX® AND</u> CAUSES OF ACTION AGAINST MERCK (COUNTS I – VI)

15-108. Answering Paragraphs 15 through 108 of Plaintiff's Complaint, Defendant states that allegations in these paragraphs of the Complaint are not directed toward Defendant, and, therefore, no response is required. To the extent that a response is deemed required, Defendant states that Plaintiff fails to provide the proper context for the allegations in these paragraphs of the Complaint, and Defendant lacks knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same.

# **CAUSES OF ACTION AGAINST PFIZER**

# **COUNT VII (NEGLIGENCE)**

- 109. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.
- 110. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 111. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 112. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.
- 113. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe

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and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

- 114. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 115. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 115 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

# COUNT VIII (BREACH OF EXPRESS WARRANTIES)

- 116. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.
- 117. Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

- 118. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 119. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 120. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 120 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

# COUNT IX (BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS)

- 121. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.
- 122. Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the

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potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

- 123. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 124. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
  - 125. Defendant denies the allegations in this paragraph of the Complaint.
- 126. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

127. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 127 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

# **COUNT X (NEGLIGENT MISREPRESENTATION)**

- 128. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.
- 129. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 130. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 131. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

- 132. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 133. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 134. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 135. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

136. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 136 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

### **COUNT XI (FRUADULENT MISREPRESENTATION)**

- 137. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.
- 138. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 139. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 140. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

- 141. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 142. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 143. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 144. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 144 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

# DISCOVERY RULE AND FRAUDULENT CONCEALMENT

145. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that allegations in this paragraph of the Complaint regarding Vioxx® are not directed

toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

- 146. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that allegations in this paragraph of the Complaint regarding Merck are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 147. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 148. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant

admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Merck are not directed toward Defendant, and, therefore, no response is required. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

### **GENERAL DENIAL**

Defendant denies all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

# **ADDITIONAL DEFENSES**

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

#### **First Additional Defense**

The Complaint fails to state a claim upon which relief can be granted.

#### **Second Additional Defense**

Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

#### **Third Additional Defense**

At all relevant times, Defendant's warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

# **Fourth Additional Defense**

Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendant.

#### **Fifth Additional Defense**

Plaintiff's action is barred by the statute of repose.

# **Sixth Additional Defense**

Plaintiff's claims against Defendants may be barred, or Plaintiff's damages may be reduced, under the doctrine of comparative negligence as set forth in M.G.L. c. 231, §85.

#### **Seventh Additional Defense**

Plaintiff's damages, if any, may have been caused by, or were the result of, independent, intervening, and/or superseding forces and or actions or inactions of third parties over whom Defendants had no control or right of control.

# **Eighth Additional Defense**

Any injuries or expenses incurred by Plaintiff was not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

#### **Ninth Additional Defense**

Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's treating and prescribing physicians. Plaintiff's claims are therefore barred by the Learned Intermediary Doctrine.

#### **Tenth Additional Defense**

Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendant and any liability of Defendant is therefore barred.

#### **Eleventh Additional Defense**

Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

#### **Twelfth Additional Defense**

Plaintiff had or should have had full knowledge of, accepted, and assumed all risks and possible adverse affects related to the use of Celebrex®. Plaintiff's recovery, therefore, is barred, diminished, reduced, or offset under the principles of assumption of the risk and/or informed consent.

#### **Thirteenth Additional Defense**

Plaintiff is barred from recovering against Defendant because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

#### **Fourteenth Additional Defense**

Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

#### Fifteenth Additional Defense

The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

#### Sixteenth Additional Defense

Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

#### **Seventeenth Additional Defense**

Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

#### **Eighteenth Additional Defense**

Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

#### **Nineteenth Additional Defense**

Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

#### **Twentieth Additional Defense**

Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

# **Twenty-first Additional Defense**

Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

# **Twenty-second Additional Defense**

To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

# **Twenty-third Additional Defense**

Defendant affirmatively avers that the imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitution of the Commonwealth of Massachusetts, and would additionally violate Defendant's rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

# **Twenty-fourth Additional Defense**

Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

# **Twenty-fifth Additional Defense**

The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

# **Twenty-sixth Additional Defense**

Plaintiff's punitive damage claims are preempted by federal law.

# **Twenty-seventh Additional Defense**

Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

# **Twenty-eighth Additional Defense**

To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

# **Twenty-ninth Additional Defense**

Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

# **Thirtieth Additional Defense**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the Commonwealth of Massachusetts. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial

court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

# **Thirty-first Additional Defense**

The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

# **Thirty-second Additional Defense**

The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

#### **Thirty-third Additional Defense**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

#### **Thirty-fourth Additional Defense**

Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

# **Thirty-fifth Additional Defense**

Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or

illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

# **Thirty-sixth Additional Defense**

The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

# Thirty-seventh Additional Defense

The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

# Thirty-eighth Additional Defense

The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

# **Thirty-ninth Additional Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

### **Fortieth Additional Defense**

The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the

Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

# **Forty-first Additional Defense**

Plaintiff's claims for punitive damages cannot be sustained because such damages are barred by Massachusetts law.

#### **Forth-second Additional Defense**

Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

WHEREFORE, Pfizer respectfully requests that this Court:

- 1. Dismiss the Plaintiff's Complaint with prejudice;
- 2. Enter judgment in Pfizer's favor as to all causes of action asserted against it;
- 3. Award Pfizer its costs for this lawsuit;
- 4. Apportion Plaintiff's award among all entities whose conduct contributed to the claimed injuries and damages; and
- 5. Grant such other and further relief as the Court deems just and appropriate.

# **JURY DEMAND**

Defendant hereby demands a trial by jury as to all issues so triable.

Respectfully submitted,

PFIZER INC. By its attorneys,

J. Christopher Allen, Jr.

Joseph J. Leghorn (BBO # 292440) J. Christopher Allen, Jr. (BBO # 648381) NIXON PEABDOY LLP 100 Summer Street Boston Massachusetts 02110-1832 (617) 345-1000

# **CERTIFICATE OF SERVICE**

I, J. Christopher Allen, Jr., do hereby certify that a true copy of the above document was served upon all counsel of record by electronic service this 8th day of November, 2007.

J. Christopher Allen, Jr.

J. Christopher Allen, Jr.